09-19-00

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Practitioner's Docket No. 55,106 (1699) *PATENT*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s): **Russell H. TAYLOR**
Robert Charles SUSIL

WARNING: *37 CFR 1.41(a)(1) points out:*

"(a) A patent is applied for in the name or names of the actual inventor or inventors.

(1) The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by § 1.63, except as provided for in § 1.53(d)(4) and § 1.63(d). If an oath or declaration as prescribed by § 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to § 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in § 1.17(i) is filed supplying or changing the name or names of the inventor or inventors."

For (title): **METHODS AND SYSTEMS FOR IMAGE-GUIDED SURGICAL INTERVENSIONS**

CERTIFICATION UNDER 37 C.F.R. 1.10*
*(Express Mail label number is **mandatory**.)*
(Express Mail certification is optional.)

I hereby certify that this correspondence and the documents referred to as attached therein are being deposited with the United States Postal Service on this date September 18, 2000, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EL196832898US addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Peter F. Corless
(type or print name of person mailing paper)

Signature of person mailing paper

WARNING: *Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.*

WARNING:* *Each paper or fee filed by "Express Mail" **must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).*
*"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442*

1. Type of Application

This new application is for a(n)

(check one applicable item below)

[X] Original (nonprovisional)

[ ] Design

[ ] Plant

WARNING: ***Do not*** *use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4), unless the International Application is being filed as a divisional, continuation or continuation-in-part application.*

WARNING: ***Do not*** *use this transmittal for the filing of a provisional application.*

NOTE: If one of the following 3 items apply, then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION.

[ ] Divisional.

[ ] Continuation.

[ ] Continuation-in-part (C-I-P).

2. Benefit of Prior U.S. Application(s) (35 U.S.C. 119(e), 120, or 121)

NOTE: A nonprovisional application may claim an invention disclosed in one or more prior filed copending nonprovisional applications or copending international applications designating the United States of America. In order for a nonprovisional application to claim the benefit of a prior filed copending nonprovisional application or copending international application designating the United States of America, each prior application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. 112. Each prior application must also be:

(i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or

(ii) Complete as set forth in § 1.51(b); or

(iii) Entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and include the basic filing fee set forth in § 1.16; or

(iv) Entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(l) within the time period set forth in § 1.53(f).

37 CFR 1.78(a)(1).

NOTE *If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.*

WARNING: *If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.*

WARNING: *When the last day of pendency of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, any nonprovisional application claiming benefit of the provisional application* ***must*** *be filed prior to the Saturday, Sunday, or Federal holiday within the District of Columbia. See 37 C.F.R. § 1.78(a)(3).*

[ ] The new application being transmitted claims the benefit of prior U.S. application(s). Enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

3. Papers Enclosed

A. Required for Filing Date under 37 C.F.R. 1.53(b) (Regular) or 37 C.F.R. 1.153 (Design) Application

___ Pages of Specification
___ Pages of Claims
___ Sheets of Drawing
[ ] Formal
[ ] Informal

B. Other Papers Enclosed

__1__ Pages of Abstract
_____ Other

WARNING: ***DO NOT*** *submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. For comments on proposed then-new 37 C.F.R. 1.84, see Notice of March 9, 1988 . . . (1990 O.G. 57-62).*

NOTE: *"Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawing a minimum distance of 1.5 cm. (5/8 inch) down from the top of the page." 37 C.F.R. 1.84(c)).*

(complete the following, if applicable)

[ ] The enclosed drawing(s) are photograph(s), and there is also attached a "PETITION TO ACCEPT PHOTOGRAPH(S) AS DRAWING(S)." 37 C.F.R. 1.84(b).

4. Additional Papers Enclosed

[ ] Preliminary Amendment
[ ] Information Disclosure Statement (37 C.F.R. 1.98)
[ ] Form PTO-1449
[ ] Citations
[ ] Declaration of Biological Deposit
[ ] Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.
[ ] Authorization of Attorney(s) to Accept and Follow Instructions from Representative
[ ] Special Comments
[ ] Other:

5. Declaration or Oath

NOTE: A newly executed declaration is not required in a continuation or divisional application provided the prior nonprovisional application contained a declaration as required, the application being filed is by all or fewer than all the inventors named in the prior application, there is no new matter in the application being filed, and a copy of the executed declaration filed in the prior application (showing the signature or an indication thereon that it was signed) is submitted. The copy must be accompanied by a statement requesting deletion of the names of person(s) who are not inventors of the application being filed. If the declaration in the prior application was filed under § 1.47 then a copy of that declaration must be filed accompanied by a copy of the decision granting § 1.47 status or, if a nonsigning person under § 1.47 has subsequently joined in a prior application, then a copy of the subsequently executed declaration must be filed. See 37 CFR 1.63(d).

NOTE: A declaration filed to complete an application must be executed, identify the specification to which it is directed, identify each inventor by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and the residence, post office address and country of citizenship of each inventor and state whether the inventor is a sole or joint inventor. 37 CFR 1.63(a)(1)-(4).

[ ] Enclosed

Executed by

(check **all** *applicable boxes)*

[ ] inventor(s).
[ ] legal representative of inventor(s). 37 CFR 1.42 or 1.43.
[ ] joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.
  [ ] This is the petition required by 37 CFR 1.47 and the statement required by 37 CFR 1.47 is also attached. See item 13 below for fee.

[X] Not Enclosed.

NOTE: *Where the filing is a completion in the U.S. of an International Application, or where the completion of the U.S. application contains subject matter in addition to the International Application, the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.*

[ ] Application is made by a person authorized under 37 C.F.R. 1.41(c) on behalf of *all* the above named inventor(s).

(The declaration or oath, along with the surcharge required by 37 CFR 1.16(e), can be filed subsequently).

NOTE: It is important that all the correct inventor(s) are named for filing under 37 CFR 1.41(c) and 1.53(b).

[ ] Showing that the filing is authorized.
(not required unless called into question. 37 CFR 1.41(d))

6. Inventorship Statement

WARNING: *If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.*

The inventorship for all the claims in this application are:

[ ] The same.

or

[ ] Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,
[ ] is submitted.
[ ] will be submitted.

7. Language

NOTE: An application including a signed oath or declaration may be filed in a language other than English. An English translation of the non-English language application and the processing fee of $130.00 required by 37 CFR 1.17(k) is required to be filed with the application, or within such time as may be set by the Office. 37 CFR 1.52(d).

[X] English
[ ] Non-English
[ ] The attached translation includes a statement that the translation is accurate. 37 C.F.R. 1.52(d).

8. Assignment

[ ] An assignment of the invention to _____

[ ] is attached. A separate [X] "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or [ ] FORM PTO 1595 is also attached.

[ ] was filed in the parent application
[X] will follow.

NOTE: "If an assignment is submitted with a new application, send two separate letters-one for the application and one for the assignment" Notice of May 4, 1990 (1114 O.G. 77-78).

WARNING: *A newly executed "STATEMENT UNDER 37 CFR 3.73(b)" must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993, 1150 O.G. 62-64.*

9. Certified Copy

Certified copy(ies) of application(s)

Country	Appln. No.	Filed

from which priority is claimed

[ ] is enclosed.
[ ] was filed.
[ ] will follow.

NOTE: *The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 CFR 1.55(a) and 1.63.*

NOTE: *This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. 120 is itself entitled to priority from a prior foreign application, then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.*

10. Fee Calculation (37 C.F.R. 1.16)

A. [X] Regular application

CLAIMS AS FILED

Claims	Number Filed	Basic Fee Allowance	Number Extra	Rate	Basic Fee 37 C.F.R. 1.16(a) $690.00
Total Claims (37 CFR 1.16(c))		- 20 =	0	x $ 18.00	690.00
Independent Claims (37 CFR 1.16(b))		- 3 =	0	x $78.00	
Multiple Dependent Claim(s), if any (37 CFR 1.16(d))			+	$260.00	

[ ] Amendment cancelling extra claims is enclosed.
[ ] Amendment deleting multiple-dependencies is enclosed.
[ ] Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 CFR 1.16(d).

Filing Fee Calculation $_____

B. [ ] Design application
($330.00—37 CFR 1.16(f))

Filing Fee Calculation $_____

C. [ ] Plant application
($540.00—37 CFR 1.16(g))

Filing Fee Calculation $ _____

11. Small Entity Statement(s)

[ ] Statement(s) that this is a filing by a small entity under 37 CFR 1.9 and 1.27 is (are) attached.

WARNING: *"Status as a small entity must be specifically established in each application or patent in which the status is available and desired. Status as a small entity in one application or patent does not affect any other application or patent, including applications or patents which are directly or indirectly dependent upon the application or patent in which the status has been established. The refiling of an application under § 1.53 as a continuation, division, or continuation-in-part (including a continued prosecution application under § 1.53(d)), or the filing of a reissue application requires a new determination as to continued entitlement to small entity status for the continuing or reissue application. A nonprovisional application claiming benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) of a prior application, or a reissue application may rely on a statement filed in the prior application or in the patent if the nonprovisional application or the reissue application includes a reference to the statement in the prior application or in the patent or includes a copy of the statement in the prior application or in the patent and status as a small entity is still proper and desired. The payment of the small entity basic statutory filing fee will be treated as such a reference for purposes of this section." 37 CFR 1.28(a)(2).*

(complete the following, if applicable)

[ ] Status as a small entity was claimed in prior application _____, filed on_____ from which benefit is being claimed for this application under:

35 U.S.C. § [ ] 119(e),
[ ] 120,
[ ] 121,
[ ] 365(c),

and which status as a small entity is still proper and desired.

[ ] A copy of the statement in the prior application is included.

Filing Fee Calculation (50% of **A**, **B** or **C** above) $_____

NOTE: Any excess of the full fee paid will be refunded if a small entity status is established refund request are filed within 2 months of the date of timely payment of a full fee. The two-month period is not extendable under § 1.136. 37 CFR 1.28(a).

12. Request for International-Type Search (37 C.F.R. 1.104(d))

(complete, if applicable)

[ ] Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

13. Fee Payment Being Made at This Time

[X] Not Enclosed

[X] No filing fee is to be paid at this time.
(This and the surcharge required by 37 C.F.R. 1.16(e) can be paid subsequently.)

[ ] Enclosed

[ ]	Filing fee	$_____
[ ]	Recording assignment ($40.00; 37 C.F.R. 1.21(h)) (See attached "COVER SHEET FOR ASSIGNMENT ACCOMPANYING NEW APPLICATION.")	$_____
[ ]	Petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached ($130.00; 37 C.F.R. 1.47 and 1.17(i))	$_____
[ ]	For processing an application with a specification in a non-English language ($130.00; 37 C.F.R. 1.52(d) and 1.17(k))	$_____
[ ]	Processing and retention fee ($130.00; 37 C.F.R. 1.53(d) and 1.21(l))	$_____
[ ]	Fee for international-type search report ($40.00; 37 C.F.R. 1.21(e))	$_____

NOTE: 37 CFR 1.21(l) establishes a fee for processing and retaining any application that is abandoned for failing to complete the application pursuant to 37 CFR 1.53(f) and this, as well as the changes to 37 CFR 1.53 and 1.78(a)(1), indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid, or the processing and retention fee of § 1.21(l) must be paid, within 1 year from notification under § 53(f).

Total Fees Enclosed $_____

14. Method of Payment of Fees

[Check in the amount of $_____

[ ] Charge Account No. _____ in the amount of $_____.
A duplicate of this transmittal is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b).

15. Authorization to Charge Additional Fees

WARNING: *If no fees are to be paid on filing, the following items should not be completed.*

WARNING: *Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.*

[ ] The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No._____
[ ] 37 C.F.R. 1.16(a), (f) or (g) (filing fees)
[ ] 37 C.F.R. 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

[ ] 37 C.F.R. 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)
[ ] 37 CFR 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a).
[ ] 37 C.F.R. 1.17 (application processing fees)

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 CFR 1.136(a)(3).

[ ] 37 C.F.R. 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b)).

NOTE: 37 CFR 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . issue fee." From the wording of 37 CFR 1.28(b), (a)

notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

16. Instructions as to Overpayment

NOTE: ". . . Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 CFR 1.26(a).

[ ] Credit Account No. 04-1105 .

[ ] Refund

SIGNATURE OF PRACTITIONER

Reg. No. 33,860

Peter F. Corless
(type or print name of practitioner)

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Intellectual Property Practice
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P.O. Address

Tel. No.: (617) 523-3400

Boston, MA 02109

Customer No.:

[ ] **Incorporation by reference of added pages**

(check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED)

[ ] Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed

Number of pages added _____

[ ] Plus Added Pages for Papers Referred to in Item 4 Above

Number of pages added _____

[ ] Plus added pages deleting names of inventor(s) named on prior application(s) who is/are no longer inventor(s) of the subject matter claimed in this application.

Number of pages added _____

[ ] Plus "Assignment Cover Letter Accompanying New Application"

Number of pages added _____

[X] **Statement Where No Further Pages Added**

(if no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item)

[X] This transmittal ends with this page.

#117456

Docket: 55106

Express Mail Label No.: EL96832898US

METHODS AND SYSTEMS FOR IMAGE-GUIDED SURGICAL INTERVENTIONS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to methods and systems for image-guided effector placement. Methods and systems of the invention of the invention enable minimally invasive image-guided interventions with a single cross-sectional image and without the use of a sterotactic frame or separate fidicuial apparatus. Preferred systems of the invention include a localization module, integrated with a medical instrument, that allows for localization of the effector in targeted image space using a single cross-sectional image.

2. Background

Percutaneous procedures, i.e. through the skin procedures, require one to find the position of an internal target, e.g. organ, tumor, etc., without direct visualization. Most often, this involves registration of an image data set, in which the target is identified, with physical space. This procedure, stereotaxy, was reported early by Clarke and Horsley (Clarke, *Brain* (1905) 28:12-29). Most techniques have been based upon the attachment of a rigid frame to a patient, providing a common coordinate system through which the image and physical spaces can be related (Galloway, in *Interactive Image-Guided Neurosurgery. American Association of Neurologic Surgeons* (1993) 9-16). While stereotactic procedures were initially advanced using two-dimentional imaging modalities, the advent of three dimensional imaging systems including Computed Tomography (CT) in the 1970's greatly accelerated development and applications. Instead of projecting three-dimensional structures into two-dimensions, this modality provides a series of 2D image slices, allowing for true three-dimensional reconstruction.

The Brown-Roberts-Wells (BRW) frame consisting of three N shaped motifs attached to a patient's skull, represented a major advance in localization (Brown, *Invest Radiol* (1979) 14:300-304). Previous frames were constrained to remain strictly perpendicular to the image plane, providing little flexibility (Galloway, in *Interactive Image-Guided Neurosurgery. American Association of Neurologic Surgeons* (1993) 9-16). However, the BRW frame was more versatile in that the position and orientation of the frame was fully encoded within each image slice such that the position of a point was defined in both the frame space and the image space coordinate systems allowing for rotations and tilting of the frame relative to the image plane (Brown, *Invest Radiol* (1979) 14:300-304).

A number of systems use a rigid stereotaxic frame wherein the frame is attached to the patient. These devices tend to be large and unwieldy contraptions that limit the effective application time of the frame to less than a day. Consequently, the frame must be recalibrated before each use. A system was implemented for image guide intracranial needle placement using biplanar x-ray and a fixed head frame (Lavallee, *Computer Integrated Surgury: Technology and Clinical Applications*, (1996) p 343-351). In another neurosurgical system, a surgical plan using multiple CT image slices, register by docking their robot with the patient's stereotactic head frame, and then place the needle without CT surveillance (Kwoh, *IEEE Trans Biomed Eng* (1988) 35:153-160). In another system a stereotactic head frame is used to register the robot and image space, but are able to perform needle placement under active CT surveillance to confirm the position of their end effector (Glauser, *Second Annual International Symposium on MRCAS* (Nov. 1995)). Similarly, a method wherein the placement and register of a needle under biplanar fluoroscopy, was developed in order to access mobile organs (e.g. the kidneys) (Bzostek et al. *The First Joint Conference of CVRMed and MRCAS,* (March 1997) Grenoble, France).

Surgically implanted fiducial markers have been employed to generate reference frame in the patient and have been affixed to the bones, in particular the cranium, to prevent the marker from shifting with time. These implant systems have been used for image-guided applications in the brain where the cranium is readily accessible for surgical implantation of fiducial markers. Surgical pins and screws for permanently affixing fiducial implants to a patient bone are reported in U.S. Patents 5,397,329 and 5,6369,255 such that pegs, pins or screws comprising a scanner opaque object are surgically implanted into one or more bones such as the cranium, sternum or vertabrae. Fiducial markers that are implanted into the patient's soft tissue are reported in U.S. Patents 5,941,890 and 6,056,700.

While these implanted markers are fixed within the body and are unlikely to move, there are several drawbacks to their use. Implantation requires surgery wherein the markers are inserted or driven into the bones raising the concern of cracking or otherwise damaging the support bone in the implantation process. Further surgical procedures increase patient discomfort, hospital stays or recovery time and the risk of complications such as infection or bone damage.

It thus would be desirable have improved methods and systems to determine the location of an end effector delivery system and the location of an effector such as a needle, probe, etc. within a body. It would be further desirable to have such a position and orientation system that could be employed in minimally invasive surgical procedures without need for external reference frames, surgically implanted fiducial markers or calibration procedures.

SUMMARY OF THE INVENTION

We have now discovered image registration systems for determining the three-dimensional position and orientation of a medical instrument (effector) such as a needle, probe, etc. relative to a subject using one or more cross sectional images of the subject. Significantly, methods and systems of the invention enable effector placement without use of patient immobilization or separate fiducial implantation.

More particularly, we have discovered that by placement of a fiducial object separate from a patient but in association with a medical instrument, a single cross-sectional image can be taken via an imaging device such as Computed Tomography, Magnetic Resonance Imaging or ultrasound, and that single image employed to directly manipulate and orient the medical instrument during the course of a surgical procedure.

That is, the invention includes use of an imaging system that comprises an imaging apparatus and a medical instrument with an associated fiducial object that can be imaged in the same image (cross-sectional image) as a targeted site of the patient (e.g. a tumor, organ, etc.); a medical image (cross-sectional image) is obtained that comprises both the fiducial object and the targeted site of the patient; and manipulating the instrument with respect to the patient using information derived from the image.

It should be appreciated that the systems and methods of the invention enable direct manipulation of a medical instrument based on a cross-sectional image.

Thus, the systems and methods of the invention enable calculating, relating and manipulation of the position of the medical instrument and target site of a patient (e.g. tumor, site for drug delivery, etc.) via the information contained in a single cross-sectional image. Prior approaches have required use of multiple reference frames to calculate relative positions of a medical instrument and a targeted site of a patient, e.g. an image is taken of a target site and a separate fiducial implant and that reference frame

related to the separate reference frame in which the medical instrument is positioned, which relation requires use of a third reference frame or overlay of the first and second reference frames. Clearly, the methods and systems of the invention are a significant advance which can effectively utilize a single reference frame to calculate, relate and manipulate relative positions of the medical instrument and target site of a patient.

Image registration systems of the invention system preferably comprise an imaging device, e.g. a scanning device such as a computed topography (CT) or magnetic resonance imaging (MRI) scanner or an imaging ultrasound device. The imaging device is in communication with a surgical instrument, e.g. an effector such as a needle, probe, drug delivery device, and the like. The medical instrument has an associated fiducial object (e.g. localization module) that enables generating three identifiable points via a cross-sectional image to coordinate pose of the instrument with respect to a targeted site of the patient. The fiducial object may be e.g. integral to the instrument, or attached or otherwise affixed to the instrument. The fiducial object also may be separate from the instrument but nevertheless associated therewith provided the fiducial object and the instrument maintain a fixed spatial relationship.

The imaging device typically is in communication with one or more surgical instruments and can provide substantially contemporaneous communication of data provided by the imaging and corresponding manipulation of the instrument(s). That is, the apparatus and methods of the invention provide an active registration system whereby a subject is being imaged, e.g. positioned within a CT or MRI scanner, permitting direct and substantially contemporaneous visualization and confirmation of the location of effector, and anatomical structures during effector placement.

The imaging device yields a cross-sectional image that provides three identifiable points on the insector plane between the targeted site (e.g. lesion, tumor, site of drug delivery) and the surgical instrument. Those three identified points, obtained via a single

cross-sectional image, can enable high precision manipulation of the instrument. That is, image registration systems of the invention can allow for a precise localization of the effector in the image space relative to the subject using a single cross-sectional image.

Multiple cross-sectional images also can be employed, particularly to enhance accuracy (e.g. by averaging multiple images) and to compensate for patient motion during the course of a surgical procedure. The multiple images are typically obtained over a period of time, e.g. at least about one or two minutes, or over the course of about three, four, five or more minutes. A volumetric image also may be obtained. Multiple images also may be obtained quite rapidly, e.g. multiple images obtained each second, and such rapid imaging extended over the course of a medical procedure.

Image guidance systems of the invention are advantageously employed in percutaneous surgical procedures for localized therapy delivery and diagnostic biopsy, with distinct advantages over prior percutaneous placement techniques. For example, while previous techniques have relied on methods that only register the device space once; the active single image guidance system is able to perform a registration for every scanned image slice. The effector (medical instrument) and patient are contained within the cross sectional imager such that images can be taken at any point for confirmation of effector location. An operator can then directly visualize and confirm when an effector such as a needle, probe, etc. has reached the desired target. In addition, image guidance can be employed to avoid contacting or otherwise damaging sensitive structures (such as vascular tissue). In soft tissues, such as the liver, monitoring progress with additional scanned images allows the operator to adjust the target and effector trajectory to compensate for tissue deformation. This allows for frequent positive confirmation of position and pose of the effector that is a significant safety advantage. Specific applications of percutaneous procedures include but are not limited to prostate biopsy and therapy delivery, access to the spine and liver biopsy.

The systems and methods of the invention provide significant additional advantages. Systems of the invention can effect controlled, well-planned movements of the effector with high localization accuracy and error attenuation over a large range of positions and orientations such that the risk of inadvertent motion is minimized. In addition, when using imaging modalities that involve ionizing radiation (such as CT), robotic positioning of the effector can reduce or eliminate operator (e.g. physician, technician, etc.) exposure to harmful emissions. This system is markedly less invasive than previous techniques whereby surgical morbidity, patient discomfort and duration of recovery time/hospitalization are reduced.

Systems and methods of the invention can be employed for a wide variety of therapeutic regimes. For example, a variety of materials deposited or administered to the patient by the systems and methods of the invention, such as therapeutic agents e.g. chemotherapeutics, DNA therapeutics (gene therapy), radiation seed implant, antibacterial agent, and the like; ethanol; a sclerotic solution; energy such as e.g. high intensity ultrasound, directed beam therapy, localized X-ray therapy, photodynamic therapy, laser ablation therapy, RF ablation therapy, and the like; energy removal from a patient such as cryotherapy; tissue removal such as removal of a tumor, biopsy sample, etc.

Other aspects of the invention are discussed *infra*.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 shows schematically a preferred image registration system and operation cycle thereof of the invention. Data is made available to both the user and a therapy planning system to provide a treatment plan. Therapy is executed via a robotically controlled end effector.

FIG. 2 (which includes FIGS. 2A and 2B) shows a preferred localization device attached to the end effector (medical instrument) for use in the systems and methods of the invention. When inserted into the image field of view, a cross section of each of the fidicual bars (nine) can appear in the scanning image (e.g. CT or MRI), allowing for registration.

FIG. 3 (which includes FIGS. 3A and 3B) shows dimensioning and coordinate system conventions for fiducial motifs (FIG. 3A), and one fiducial motif intersected by the image plan, where p1, p2, and p3 are the three fiducial bar points of intersection with the image plan, and f, ϕ and θ define the orientation of the image plan relative to the fiducial motif (f = fraction of distance along the diagonal fiducial where intersection occurs) (FIG 3B).

DETAILED DESCRIPTION OF THE INVENTION

As discussed above, a registration system is provided for determining the three-dimensional position and orientation of an effector such as a needle, probe, etc. relative to a subject using one or more cross sectional images of the subject. The image registration system suitably comprises a scanning device such as a CT, MRI or the like, a fiducial object (i.e. that can be detected by the imaging apparatus) associated with a surgical instrument. Systems and methods of the invention enable effector placement without use of patient immobilization or separate fiducial implantation.

In particular, systems and methods of the invention provide a fiducal object representation in a single cross-sectional image that is unique for the pose of the instrument within the therapeutic field(i.e. the targeted treatment area of the patient) or range of motion of the medical instrument with which the fiducial object is associated.

By stating that a fiducial object is associated with a medical instrument (e.g. probe, needle/needle driver, etc.), it is indicated that the fiducial object is an integral component of the medical instrument, attached to the medical instrument (e.g. by adhesive, etc.), or where the fiducial object is separately (without physical attachment) positioned from the medical instrument but the medical instrument and the fiducial object maintain a fixed relationship.

Referring now to the various figures of the drawing wherein like reference characters refer to like parts, FIG. 1 schematically illustrates one preferred embodiment 100 of single registration system in accordance with the present invention. Here, a patient 20 is located within an imager 30 whereby patient image data 110 is collected and transferred to a control apparatus 120. A user interface 300 interacts with the control apparatus 120 to display localization information and to receive information from the user. The therapy planning unit 350 also interacts with the control system 120 and the user 10 to arrive at a treatment plan. The control apparatus 120 directs a robotic end effector 200 that controls a therapy delivery unit 250 located within the imager 30. A fiducial object (localization device) 210 is mounted on the end effector 200. The progress of the therapy delivery unit 250 in applying the treatment plan can be monitored in real-time by imager 30 feedback wherein the position of the therapy delivery unit 250 is determined relative to the target from a single image 114 comprising a cross section of the patient 20, the therapy delivery unit 250 and the localization device 210.

The robotic end effector 200 comprises a mounting site for the fiducial object 210, a device to hold an effector or therapy delivery unit 250 such as a needle, probe, etc. and a robotic arm or other device that is capable of translating the held effector in three dimensions with a relatively wide range of motion, e.g. at least 3 degrees of motion, more preferably at least about 4, 5, 6, 7, 8, 9 or 10 degrees of motion. Preferably, the robotic arm has at least 4 or more preferably at least about 5 degrees of motion such that the held effector can be located at any specified physical location in any specified orientation.

In order to register the therapy delivery unit 250 to the image space, the control system 120 has to identify a set of three corresponding points in both the robotic end effector 200 (holder) coordinate system, *H*, and the image coordinate system, *I*. These three points define a coordinate system *P*. By finding the position and orientation of *P* in the image space, ${}^{I}_{P}T$, and the holder space, ${}^{H}_{P}T$, the control system 120 can then determine the pose of the robotic end effector (holder) in the image coordinate system, ${}^{I}_{H}T={}^{I}_{P}T\left({}^{H}_{P}T\right)^{-1}$. The calibration of the robotic end effector 200 (holder), *H*, and the therapy delivery unit 250 (needle), *N*, coordinate systems ${}^{H}_{N}T$, were previously performed whereby the control apparatus 120 can find ${}^{I}_{N}T$, the pose of therapy delivery unit 250 (needle) in the image space.

In order to find the set of three corresponding points in both the image and holder coordinate systems using only one cross sectional image, a fiducial object 210 is employed wherein the device uses the Brown-Roberts-Wells frame (Brown, *Invest Radiol* (1979) 14:300-4). The Brown-Roberts-Wells frame is merely illustrative and other approaches can be utilized that can uniquely identify three distinct points.

Now referring to FIG 2, the basic structural element of the fiducial object 210 is a 'N' shaped fiducial motif 214. Preferably, this motif is repeated three times, forming a 'U' shaped module with one fiducial motif 214 as a base and the other two fiducial motifs as sides. The fiducial object 210 is attached to the robotic end effector 200 in such a way that the localization device is within the imager field of view. Preferably the localization device 210 is rigidly attached to the robotic end effector 200. More preferably the localization device 210 is attached using at least four screws. The material used for the fiducial motifs 214 is opaque to imager 30 radiation and they are supported by or embedded in a material that is transparent to imager 30 radiation. When the imager is a CT scanner, a metal rod is used for the fiducial motifs, preferably the metal rod is

aluminum. More preferably the metal rod is aluminum with a diameter of from about 0.1 to about 0.5 inches, preferably a diameter of about 0.25 inches. The dimensioning (L_1,L_2) and coordinate system (x,y) for the fiducial motif 214 is illustrated in FIG. 3A. Preferably, L_1 is about 8 inches and L_2 is about 4 inches. However, other values of L_1 and L_2 will be appropriate for localization devices employed in different applications.

A schematic illustration of one fiducial motif 214 intersected by an image plane 115 is presented in FIG. 3B wherein p_1, p_2, p_3 are the three fiducial bar points of intersection with the image plane 115. The orientation of the image plane 115 relative to the fiducial motif 214 is described by three parameters by f, the fraction of the distance along the diagonal fiducial where the intersection occurs; ϕ, the angle between the fiducial motif plane 214 and the image plane 114; and θ, the angle between the parallel fiducial bars and the line of intersection.

The control apparatus 120 can process scanned images to relate the location and pose of the end effector and effector into the image coordinate system whereby a CT image of each fiducial motif produces a cross section of the three bars, yielding three ellipses in the image. By finding the centroids of these ellipses we can locate the centers of the three bars where they intersect the image plane ${}^{I}P1$, ${}^{I}P2$, and ${}^{I}P3$. Using these three points, the control apparatus 120 can determine the position of one corresponding point, cp_n, in both the holder space, ${}^{H}cp_n$, and the image space ${}^{I}cp_n$. The control apparatus repeats this process for the remaining two fiducial motifs to generate all three corresponding points.

The distances $\left|FM_{P1\_}FM_{p2}\right| and \left|FM_{P3\_}FM_{p2}\right|$, expressed as a function of $f, \phi, and \theta$, are:

$$\left|FM_{P1\_}FM_{p2}\right| = \csc(\theta)L_2(1-f) \qquad (1)$$

$$\left|FM_{P3\_}FM_{p2}\right| = \csc(\theta)L_2(f) \qquad (2)$$

The ratio of these distance expressed in equations (1) and (2) is:

$$\left|\frac{FM_{p1\_}FM_{p2}}{FM_{p3\_}FM_{p2}}\right| = \frac{1}{f} - 1 \qquad (3)$$

The ratio (3) is only a function of f, the fraction of the distance along the diagonal fiducial where the intersection occurs. Because the transformation form the fiducial motif coordinate system to the image space is a rigid body transformation, the control apparatus 120 can determine the point where the image plane intersects the diagonal bar FM_{p2}, by finding the ratio of the distances between points ${}^{I}P_1$, ${}^{I}P_2$, and ${}^{I}P_3$. From a previous calibration of the robotic end effector 200 (holder), the control apparatus 120 knows the transformation for this point, FM_{p2}, to the holder coordinate system, ${}^{H}_{FM}T$. Therefore, control apparatus 120 knows the position of this intersection in both the image space ${}^{I}p_2$, and the holder space ${}^{H}p_2$, providing one of the three corresponding points, cp_1. The control apparatus 120 repeats this process for the two remaining fiducial motifs, generating all three corresponding points, cp_1, cp_2 and cp_3.

With the set of three point generated by the intersection of each of the three fiducial motifs and the image plane, the control apparatus 120 can do more than determine one corresponding point in the image holder coordinate systems. For example the control apparatus can further determine the angle θ (Figure 3b), but there is very little accuracy in determining this angle. When operating about $\theta = 90°$, the sensitivity of our

assessment of $\theta(\partial\theta_{measured}/\partial\theta_{actual})$ is zero. In contrast, determination of the corresponding point has much more attractive properties.

To robustly determine the corresponding points, the localization method must have two properties. First, the assessment of ${}^{H}cp_n$ should be relatively insensitive to small measurement errors in $\left|{}^{I}p_1-{}^{I}p_2\right|$ and $\left|{}^{I}p_3-{}^{I}p_2\right|$. These sensitivities to measurement error are:

$$\frac{\partial c}{\partial\left|{}^{I}p_1-{}^{I}p_2\right|_{measured}} = -f\sqrt{1+\left(\frac{L_1}{L_2}\right)^2}\sin(\theta) \tag{4}$$

$$\frac{\partial c}{\partial\left|{}^{I}p_3-{}^{I}p_2\right|_{measured}} = (1-f)\sqrt{1+\left(\frac{L_1}{L_2}\right)^2}\sin(\theta) \tag{5}$$

Near the operating point (θ =90° and f=0.5), the magnitudes of he sensitivities are 0.71. As θ decreases, the system becomes less sensitive to measurement errors. The worst case measurement error sensitivity is 1.41. However these sensitivity values improve by decreasing the L_1/L_2 ratio.

The second property requires the measured parameters, $\left|{}^{I}p_1-{}^{I}p_2\right|$ and $\left|{}^{I}p_3-{}^{I}p_2\right|$ be sensitive to small changes in c, the distance from the image plane intersection with the diagonal fiducial to the fiducial motif origin (i.e. $c = f\sqrt{L_1^2+L_2^2}$) (Figure 3b). This sensitivity is:

$$\frac{\partial\left|{}^{I}p_1-{}^{I}p_2\right|}{\partial c} = -\csc(\theta)\Big/\sqrt{1+\left(\frac{L_1}{L_2}\right)^2} \tag{6}$$

$$\frac{\partial \left| {}^{I}p_3 - {}^{I}p_2 \right|}{\partial c} = \csc(\theta) \Big/ \sqrt{1 + \left(\frac{L_1}{L_2} \right)^2} \qquad (7)$$

At the operating point of θ =90°, the magnitudes of the sensitivities are 0.71, which is the worst case for the system. As θ decreases, the sensitivity increases. Also, as discussed above, the system sensitivity improves by decreasing the L_1/L_2 ratio.

Applications of the localization methods of the invention are numerous. One preferred application is for percutaneous tissue biopsy within the abdominal cavity. Briefly, a patient is placed in the CT scanner and a complete set of images in the area of interest is collected. Next, while the patient remains in the scanner, the physician selects a biopsy target (e.g. a tumor) and a skin entry site from the image set. A robot, with biopsy needle and effector and fiducial object, is positioned such that the fiducial object is within the imager field of view. Next, a single image is taken, containing both the biopsy target and a cross section of the fiducial object. From this one image, the necessary translation and rotation to reach the target is determined and subsequently executed by the robot. The robot, or an attendant surgeon, can then drive the biopsy needle. Because the patient remains within the scanner, a single image will confirm that the needle has reached the target site. The biopsy is then taken, completing the procedure quickly and with minimal invasiveness.

The above discussion use includes use of a CT scanning system. However, it is understood that a variety of other three-dimensional scanning cross sectional methodologies can be employed, including use of an MRI or a scanning ultrasound.

As also discussed above, the systems and methods of the invention are suitably employed for a variety of therapeutic applications such as administration of therapeutics, administration of energy sources to a patient; energy removal from a patient; tissue removal from a patient; and the like. Potential disorders and diseases that can be treated

with systems and methods of the invention include treatment of cancers (e.g. by administration of a chemotherapeutic, administration of radiation or other energy source to a tumor, surgical removal of a tumor, etc.); removal of a blockage e.g. in coronary surgery; etc.; directed or localized therapeutic administration such as for gene therapy; and the like.

All documents mentioned herein are incorporated herein in their entirety. The following non-limiting example is illustrative of the invention.

EXAMPLE 1

To determine the accuracy of the single image localization system a localization system was examined wherein the effector was a needle. The single slice determination of the needle pose, ${}^{I}_{N}T_{SS}$, was compared to the multislice ground truth determination of needle pose, ${}^{I}_{N}T_{MS}$. An average of 13 images were obtained with the robotic end effector (holder) in each of 5 different poses. All images were obtained in a GE Genesis CT Scanner wherein image slices were 5 mm thick and the image pixels were 0.7 mm by 0.7 mm. Error is defined as the difference between the multislice determined ground truth and the single slice determined pose. Components include angluar error of robotic end effector 200 (holder) pose and offset error of robotic end effector (holder). From these two components, net displacement error at the needle tip, 10 cm from the center of the robotic end effector (holder) was found. The average angular error was 0.32°, the average displacement offset error was 380 microns, and the average displacement error at the needle tip was 470 microns. The displacement error probability density function was determined with a best-fit gamma distribution (λ= 2.95 and α = 0.16). The maximum error seen in the 63 images was 1.45 mm with 95 % of the needle tip displacement errors were below 1.0 mm.

Although a preferred embodiment of the invention has been described using specific terms, such description is for illustrative purposes only, and it is to be understood that changes and variations may be made without departing from the spirit or scope of the following claims.

What is claimed is:

1. An imaging system for invasive therapy of a patient, the system comprising:

an imaging apparatus that can provide a cross-sectional image of a patient;

a medical instrument comprising a fiducial object that can be imaged in the same image as a targeted site of the patient.

2. The system of claim 1 wherein the fiducial object representation in the image is unique for the pose of the instrument within the therapeutic field or range of motion of the instrument.

3. The system of claim 1 or 2 wherein the image can produce three identifiable points to coordinate pose of the instrument and the targeted site of the patient.

4. The system of any one of claims 1 through 3 wherein the instrument pose is directly manipulated in reference to the medical image.

5. The system of any one of claims 1 through 4 wherein the relative position and orientation of the medical instrument and target site of the patient can be determined from the information contained in a single cross-sectional image produced by the imaging apparatus.

6. The system of any one of claims 1 through 5 wherein the system comprises a control apparatus that can register the instrument in a detected image space and calculate instrument movement.

7. The system of any one of claims 1 through 6 wherein the control apparatus calculates the instrument pose in the image space by generating at least three corresponding points.

8. The system of any one of claims 1 through 7 wherein the fiducial object comprises three N-shaped fiducial motifs, and the three N-shaped fiducial motifs are non-coplanar.

9. The system of claim 8 wherein the three N-shaped fiducial motifs are arranged orthogonally in a U- shape with one fiducial motif forming the bottom and two fiducial motifs forming the sides.

10. The system of any one of claims 1 through 9 wherein the medical instrument is manipulated manually.

11. The system of any one of claims 1 through 10 wherein the system further comprises a robotic apparatus capable of positioning the apparatus.

12. The system of claim 11 wherein the instrument is positioned by the robot in the desired pose relative to the patient.

13. The system of any one of claims 1 through 12 wherein the imaging device is a CT, MRI or ultrasound device.

14. The system of any one of claims 1 through 13 wherein the fiducial object is affixed to the instrument.

15. The system of any one of claims 1 through 14 wherein the fiducial object is integral to the instrument.

16. A method for guiding invasive therapy in a patient, comprising:

a) providing a system that comprises an imaging apparatus and a medical instrument comprising a fiducial object that can be imaged in the same image as a targeted site of the patient;

b) obtaining a cross-sectional image that comprises both the fiducial object and the targeted site of the patient; and

c) manipulating the instrument with respect to the patient using information derived from the image.

17. The method of claim 16 wherein the relative position and orientation of the medical instrument and target site of the patient are determined from the information contained in a single cross-sectional image.

18. The method of claim 16 or 17 wherein the instrument is manipulated using information derived from a single reference frame of the relative position of the instrument and target site.

19. The method of any one of claims 16 through 18 wherein the instrument is manipulated substantially contemporaneously with respect to obtaining the image.

20. The method of any one of claims 16 through 19 wherein the instrument is manipulated based on a single image.

21. The method of any one of claims 16 through 20 wherein a plurality of images are obtained.

22. The method of claim 21 wherein the plurality of images are taken over a period of at least one minute.

23. The method of claim 21 or 22 wherein one or more volumetric images are obtained.

24. The method of any one of claims 16 through 23 wherein a material is deposited or administered to the patient by the instrument.

25. The method of claim 24 wherein the administered or deposited material is a therapeutic agent.

26. The method of any one of claims 16 through 25 wherein energy is administered to the patient.

27. The method of any one of claims 16 through 22 wherein energy is removed from the patient.

28. The method of any one of claims 16 through 25 wherein tissue is removed from the patient by the instrument.

29. The method of any one of claims 16 through 28 wherein the instrument administers to the patient a radiation seed implant, a DNA therapeutic, a chemotherapeutic agent, a cryotherapeutic treatment, a sclerotic solution, ethanol, high intensity ultrasound, directed beam therapy, localized X-ray therapy, photodynamic therapy, laser ablation therapy, or RF ablation therapy.

30. The method of any one of claims 16 through 29 wherein the fiducial object representation in the image is unique for the pose of the instrument.

31. The method of any one of claims 16 through 30 wherein the image can produce three identifiable points to coordinate pose of the instrument and the targeted site of the patient.

32. The method of any one of claims 16 through 31 wherein the instrument pose is directly manipulated in reference to the medical image.

33. The method of any one of claims 16 through 32 wherein the instrument is registered in detected image space by a control apparatus.

34. The method of claim 33 wherein the instrument is registered in the image space by the image generating at least three corresponding points.

35. The method of any one of claims 16 through 34 wherein the fiducial object comprises three N-shaped fiducial motifs, and the three fiducial motifs are non-coplanar.

36. The method of claim 35 wherein the three N-shaped fiducial motifs are arranged orthogonally in a U-shape with one fiducial motif forming the bottom and two fiducial motifs forming the sides.

37. The method of any one of claims 16 through 36 wherein the medical instrument is manipulated manually.

38. The method of any one of claims 16 through 36 wherein the instrument is manipulated by a robotic apparatus.

39. The method of any one of claims 16 through 38 wherein the imaging device is a CT, MRI or ultrasound device.

40. An imaging system for invasive therapy of a patient, the system comprising:

an imaging apparatus that can provide a cross-sectional image of a patient;

a medical instrument comprising a fiducial object that can be imaged in the same cross-sectional image as a targeted site of the patient, the image producing three identifiable points to coordinate pose of the instrument and the targeted site of the patient; and

a control apparatus that can register the instrument in detected image space and calculate instrument movement.

41. A method for guiding invasive therapy in a patient, comprising:

a) providing a system that comprises i) an imaging apparatus, ii) a medical instrument comprising an associated fiducial object that can be imaged in the same cross-sectional image as a targeted site of the patient, and iii) a control apparatus that can, via input from the imaging apparatus, register the instrument in detected image space and calculate instrument movement;

b) obtaining a cross-sectional image that comprises both the fiducial object and the targeted site of the patient, the image producing three identifiable points to coordinate pose of the instrument and the targeted site of the patient; and

c) based on input from the control apparatus, manipulating the instrument with respect to the patient using information derived from the image.

42. A method for guiding invasive therapy in a patient, comprising:

a) providing a system that comprises i) an imaging apparatus, ii) a medical instrument comprising an associated fiducial object that can be imaged in the same cross-sectional image as a targeted site of the patient;

b) obtaining a cross-sectional image that comprises both the fiducial object and the targeted site of the patient, a single image providing information sufficient to coordinate pose of the instrument and the targeted site of the patient; and

c) manipulating the instrument with respect to the patient using information derived from a single cross-sectional image.

ABSTRACT

Featured is a system to determine the three-dimensional position and orientation of an effector (a needle, probe, or other medical instrument) relative to a subject using cross-sectional images (e.g. from a CT or MRI scanner). Also provided is a method for image guided effector placement that requires no immobilization of the patient or fiducial implantation. A localization module (fiducial object) is integrated or associated with the effector allowing for the localization of the effector in the image space using a single cross-sectional image.

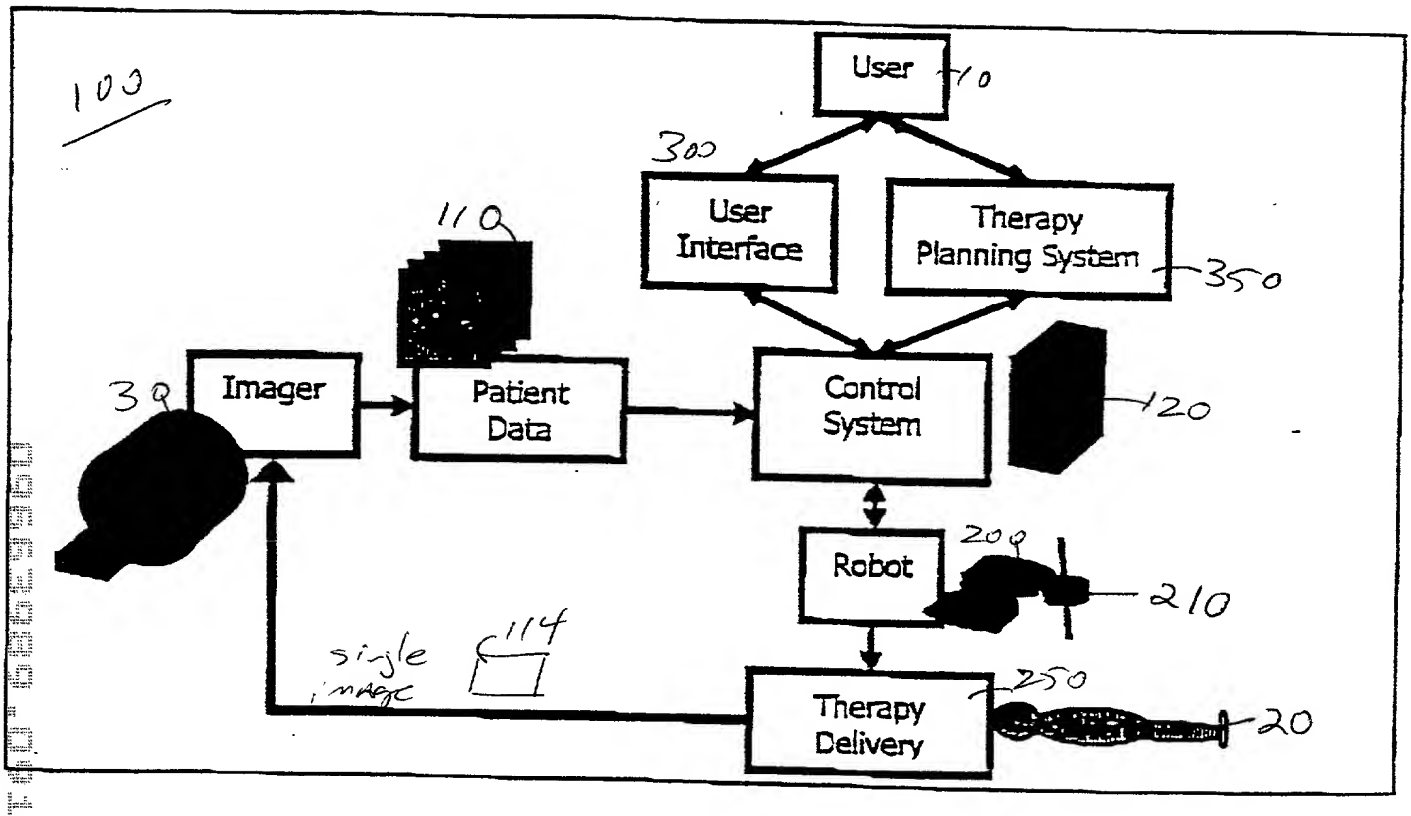
100
User
10
300
User Interface
Therapy Planning System
350
110
30
Imager
Patient Data
Control System
120
Robot
209
210
single image
114
250
Therapy Delivery
20

FIG. 1

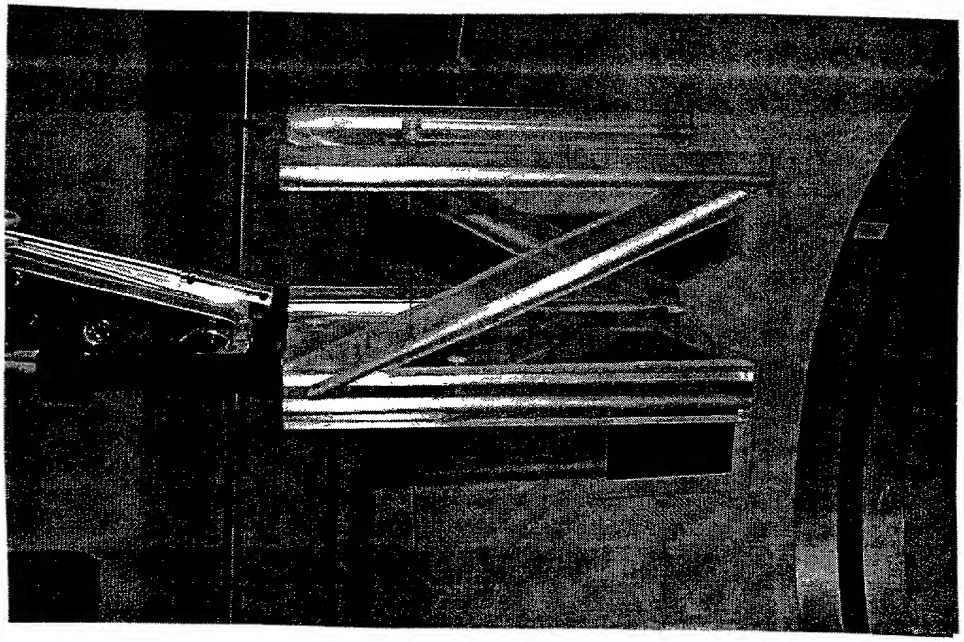

FIG. 2A

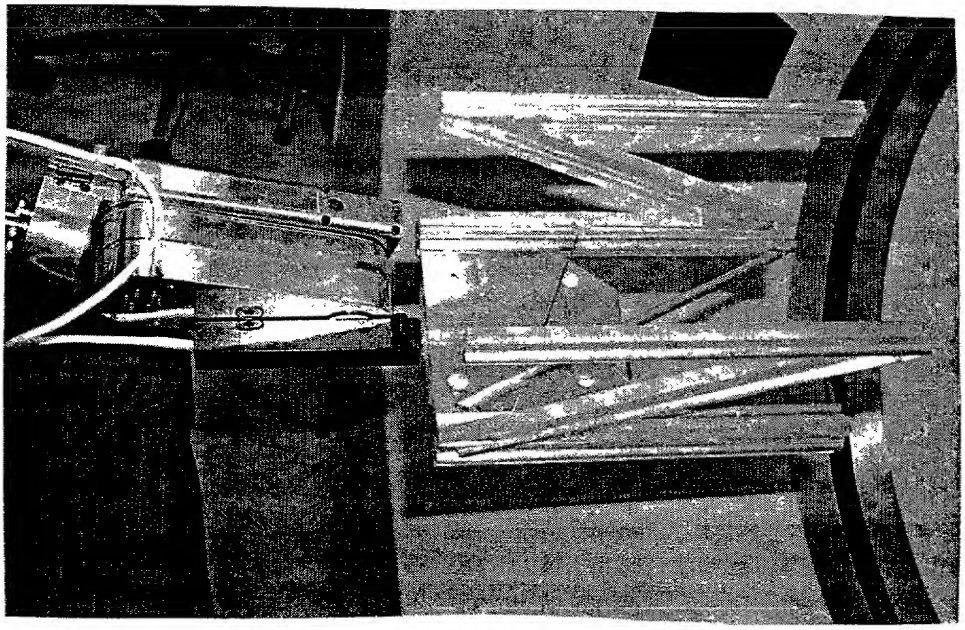

FIG. 2B

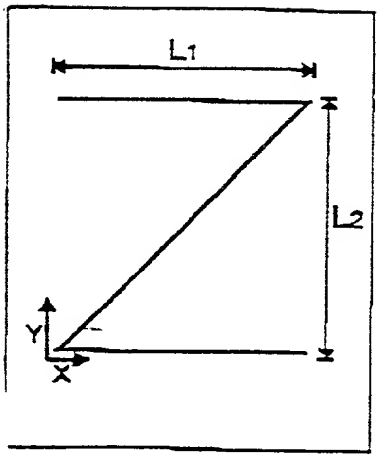

FIG. 3A

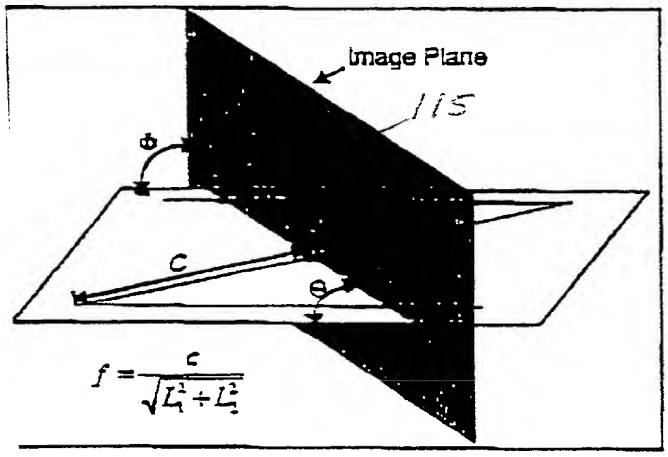

FIG. 3B